(b) expanding a portion of the catheter to provide controllable expansion of the endovascular [stent] expandable prosthesis outwardly into contact with the body passageway, by deforming a portion of the endovascular [stent] expandable prosthesis with a force in excess of the elastic limit of the portion of the [stent] expandable prosthesis, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the endovascular [stent] expandable prosthesis prevents the body passageway from collapsing, and the endovascular [stent] expandable prosthesis remains in the passageway.

REMARKS

Reconsideration of the present application is respectfully requested. This application includes claims 28-34, with claims 31-34 being substantially copied from the patent issued to Palmaz for purposes of provoking an interference between the present application and the Palmaz patent. All of the claims were rejected under 35 U.S.C. §102(a) in view of the patent to Hammerslag or under §102(e) in view of Rockey.

A new Form 1449 prior art citation form has been provided with proper class and subclass citations in accordance with the Examiner's request.

Applicant submits that claims 28, 30, 33 and 34 as originally written are readily distinguishable over the cited references. Each of these claims define inelastic expansion of the stent or prosthesis - that is, expansion upon application of a force in excess the elastic limit of the prosthesis. Neither Hammerslag nor Rockey includes this important limitation.

Hammerslag describes a synthetic liner that has elasticity compatible with the elasticity of the artery within which it is disposed. See, Hammerslag Abstract and Col. 1, lines 36-38. The object of the Hammerslag device is to expand and contract with the artery. See, Col. 2, lines 7-10. Thus, unlike

Applicant's claimed invention, the Hammerslag liner is not inelastically expanded. It is significant that the Palmaz patent, from which claims 31-34 were substantially copied, was allowed over Hammerslag. In distinguishing Hammerslag from his device, Palmaz argued that Hammerslag does not disclose or suggest inelastic expansion or controlled expansion of the liner. Palmaz also questioned the operability of the Hammerslag liner because it appeared that the elasticity of the liner would cause it to retract to its original unexpanded shape when the balloon was deflated. See, Palmaz File History.

Likewise, the Rockey patent does not disclose or suggest inelastic expansion or expansion by a force exceeding the elastic limit of the prosthesis as claimed by Applicant. The embodiments of FIGS. 1-8 of Rockey require that the ring balloons remain inflated in situ to keep the sleeve in position within the passageway. The Rockey embodiment of FIG. 9 includes an annular sleeve 51 which is filled with a fluid plastic material 66. The material 66 solidifies after the balloon 50 has been expanded to press the sleeve into contact with the passageway. It is the solidification of material 66 that keep the sleeve in its expanded second shape. There is no disclosure or suggestion in Rockey that the sleeve 51 is inelastically expanded.

It is therefore submitted that claims 28, 30, 33 and 34 as originally written are allowable over both Hammerslag and Rockey because these claims include the important non-obvious limitation of inelastic expansion of the prosthesis. This feature, among other features of Applicant's invention, is not disclosed or suggested in either of the cited references.

Claims 29, 31 and 32, while not including the inelastic expansion limitation, include other limitations, as amended, that are not disclosed in or rendered obvious by either Hammerslag or Rockey. These claims have been amended to

define the tubular prosthesis or stent as being formed by a plurality of connected elongate members. Support for this amendment is found at several locations in Applicant's disclosure, such as page 4 in which the stent is described as comprising a wire formed into a series of straight sections joined at a plurality of bends.

On the other hand, Hammerslag discloses a continuous liner for contact and conformance with the artery wall. The object of the Hammerslag device is to line the artery at a stenosis site in order to prevent the recurrence of the obstruction by protecting the artery wall. See, Col. 1, lines 16-30. The liner is formed of a material that is resistant to the deposition of material from the blood. Hammerslag does not contemplate a prosthesis formed from connected elongate members or wires which include gaps between the elongate members and which, necessarily, leaves portions of the artery wall exposed and susceptible to deposition of fatty material from the blood.

The Rockey patent describes an imperforate sleeve 51. See, Col. 6, lines 10-12. The sleeve must be fluid-tight to retain the fluid plastic material therein. See, Col. 6, lines 22-25. It is clear that a prosthesis formed from connected elongate members or wires would not be fluid-tight and would not retain the fluid plastic material contemplated by Rockey.

Claims 29, 31 and 32, as amended, are clearly distinguishable over the cited references. Neither Rockey nor Hammerslag contemplate or suggest a sleeve or liner that is discontinuous, such as Applicant's claimed prosthesis formed from connected elongate members. Thus, claims 29, 31 and 32 are allowable over the cited art.

Applicant has attempted to provoke an interference with the patent to Palmaz based upon the proposed counts 1-4, which correspond exactly to

Applicant's claims 31-34 prior to the present amendment. The following correspondence between the counts and the respective claims of Applicant and Palmaz were set forth in Applicant's prior submission:

COUNT	APPLICANT'S CLAIM	PALMAZ CLAIMS
1	31	13, 18
2	32	23, 26
3	33	1
4	34	7

It was suggested that the limitation in Palmaz claims 13, 18, 23 and 26 of intersecting elongate members is a material limitation and cannot be eliminated from Applicant's claims 31 and 32 and proposed Counts 1 and 2. Applicant has amended claims 31 and 32 to add the limitation that the prosthesis or stent is formed by a plurality of connected elongate members. This limitation is supported by Applicant's specification as set forth above. It is also apparent that Palmaz intersecting elongate members support this limitation as shown in FIG. 1A, for instance, and as described at Col. 5, lines 58-68. The Palmaz elongate members 75 and 76 are connected at the ends 72 and 73 and at the points of intersection of some of the members (see, Col. 6, lines 36-40).

As amended, Applicant's claims 31 and 32 which require connected elongate members are broader than the Palmaz claims that require intersecting members. See, M.P.E.P. §2309.01(2). It is submitted that the definition of intersecting members by Palmaz was not required by the art cited during the ex parte prosecution of that patent. Intersecting wires were shown in several references cited against the Palmaz application. For instance, a tubular wire mesh of intersecting wire members was shown in Caponigro, E.P.O. 183,372, and in Wallsten, U.K. 2,135,585. The Palmaz claims were distinguished from these references on grounds other than the intersecting aspect of the elongate members.

Applicant has proposed new Counts 1 and 2 which incorporate the amendatory language of claims 31 and 32. It is submitted that the new Counts 1 and 2 correspond substantially to claims 13 and 18, and 23 and 26, respectively. The immaterial limitation of the direction of the outwardly extending force has been eliminated for reasons discussed in Applicant's prior submission. Likewise, the limitation that the elongate members intersect has been eliminated as immaterial in view of the prior art and arguments found in the Palmaz file history.

It was further suggested that Applicant's claims 33 and 34, and corresponding Counts 3 and 4, as originally written, did not correspond substantially to Palmaz claims 1 and 7, respectively. It was indicated that Applicant's choice of the term "stent" was sufficiently different from Palmaz terms "graft" and "prosthesis", based upon the perception that a stent can connote a temporary device as opposed to a permanent type implant.

The Palmaz disclosure itself describes the expanding stainless steel stents as prior art intraluminal vascular grafts. See, Col. 1, lines 30-47. The stent formed of wire in a zig-zag pattern described in Palmaz is more commonly known in the art as the "Gianturco self-expanding stent", a predecessor to Applicant's present invention. Applicant also submits that the term "stent", read in light of Applicant's specification, connotes a permanent type implant.

However, in order to avoid any confusion that might surround the term "stent", Applicant has amended claims 31-34 to define an "expandable prosthesis". This terminology parallels the language used in the Palmaz claims and encompasses the term "stent"as used by Applicant. Applicant has proposed new Counts 1-4 which incorporate the term "expandable prosthesis".

In accordance with Applicant's amendment to claims 31-34, Applicant suggests the following as new proposed Counts 1-4:

PROPOSED COUNT 1:

An endovascular implant, comprising:

a tubular shaped expandable prosthesis formed by a plurality of connected elongate members and having a first diameter which permits intraluminal delivery of the tubular shaped expandable prosthesis into a body passageway having a lumen; and

said tubular shaped expandable prosthesis having a second, expanded diameter, upon the application from the interior of said tubular shaped expandable prosthesis of an outwardly extending force, which second diameter is variable and controlled by the amount of force applied to said tubular shaped expandable prosthesis, at least a portion of said tubular shaped expandable prosthesis being deformed by the outwardly extending force to retain said tubular shaped expandable prosthesis with the second, expanded diameter, whereby said tubular shaped expandable prosthesis may be expanded to expand the lumen of the body passageway and remain therein.

PROPOSED COUNT 2:

An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable intraluminal prosthesis formed by a plurality of connected elongate members; and

a catheter having an expandable, inflatable portion associated therewith and including means for mounting said expandable intraluminal prosthesis on said expandable, inflatable portion,

whereby upon inflation of said expandable, inflatable portion of said catheter, said expandable prosthesis is forced outwardly into contact with the body passageway to remain therein, and the expansion of said expandable prosthesis is controlled by the expansion of said inflatable portion of said catheter.

PROPOSED COUNT 3:

A method for implanting an expandable prosthesis within a body passageway comprising the steps of:

(a) disposing the expandable prosthesis upon a catheter;

(b) inserting the expandable prosthesis and catheter within the body passageway by catheterization of said body passageway; and

(c) providing controllable expansion of the expandable prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the expandable prosthesis to force the expandable prosthesis outwardly into contact with the body passageway, by deforming a portion of the expandable prosthesis with a force in excess of the elastic limit of the portion of the expandable prosthesis, to implant the expandable prosthesis within the body passageway.

PROPOSED COUNT 4:

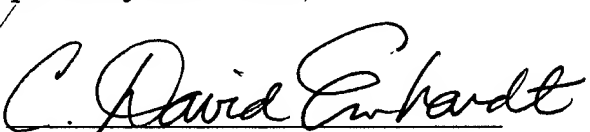
A method for expanding the lumen of a body passageway comprising the steps of:

(a) inserting an endovascular expandable prosthesis disposed upon a catheter into the body passageway until it is disposed adjacent a desired location within the body passageway; and

(b) expanding a portion of the catheter to provide controllable expansion of the endovascular expandable prosthesis outwardly into contact with the body passageway, by deforming a portion of the endovascular expandable prosthesis with a force in excess of the elastic limit of the portion of the expandable prosthesis, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the endovascular expandable prosthesis prevents the body passageway from collapsing, and the endovascular expandable prosthesis remains in the passageway.

The correspondence of these new Counts 1-4 with Applicant's claims 31 and 34 and Palmaz claims 13, 18, 23, 26, 1 and 7, has already been established above and in the prior submission. Consequently, Applicant believes that an Interference should be declared based upon the interfering subject matter defined in claims 31-34 and in the above proposed Counts 1-4. Applicant further submits that claims 28-34, as amended, define over the art of record and are, therefore, patentable to Applicant.

Respectfully submitted,

By 

C. David Emhardt
Reg. No. 18,483
Woodard, Emhardt, Naughton
Moriarty & McNett
One Indiana Square, Suite 2000
Indianapolis, Indiana 46204

(317) 634-3456